

2025 年 9 月 吉日

お客様ならびに代理店各位

Xcellerex™ XDR 50-2000L Bioreactor 用 DO probe 販売終了および代替品に関するご案内

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このたび、弊社製品 Probe, DO, Visiferm 225 (ECS Mode), Hamilton に関して、下記の通り販売終了をご案内申し上げます。最も正確な情報につきましては別添の英語版原本も併せてご参照いただきますようお願い申し上げます。

ご質問やご不明な点がございましたら、以下のバイオダイレクトラインもしくは Tech-JP までお問い合わせください。バイオダイレクトライン（製品問合せ対応窓口）TEL：03-5331-9336（音声案内②） e-mail：Tech-JP@cytiva.com

この度はご迷惑をおかけいたします。今後とも Cytiva をご愛顧賜りますようよろしくお願い申し上げます。

敬具

Cytiva（サイティバ）

バイオプロセス事業部

法人名：グローバルライフサイエンステクノロジーズジャパン株式会社

記

以下の製品につきまして、サプライヤーによる製造終了のため販売終了とさせていただきます。今後は後継品でのご利用をご検討をお願いいたします。

販売終了製品		後継品	
製品コード	製品名	製品コード	製品名
817-00145	Probe, DO, Visiferm 225 (ECS Mode), Hamilton	29749610	Sensor, DO, HAM VisiFerm RS-485 ECS, Optical, VP8

以上

Change Control Notification

Marlborough, USA, 02 September 2025

250902XDWX-1

Regarding: Discontinuation and replacement of optical dissolved oxygen (DO) sensor accessory product used with Xcellerex™ XDR 50-2000L Bioreactors

Dear Customer,

As part of the Cytiva change control program, you are hereby informed of a change regarding the replacement of an accessory probe used to measure the dissolved oxygen in the single-use assemblies for the Xcellerex™ XDR 50-2000L Bioreactors. A new probe, manufactured by the same supplier and intended as the next generation of DO probe will be provided to the customer.

Affected products

To be obsoleted Accessory	Product number
Probe, DO, VisiFerm 225 (ECS Mode), Hamilton	817-00145

Change description

The current Hamilton DO sensor (Probe, DO, VisiFerm 225 (ECB Mode)) will be replaced with a Hamilton DO sensor (Sensor, DO, HAM VisiFerm RS-485 ECS, Optical, VP8). Thus accessory 817-00145 will be discontinued and replaced with 29749610 as shown in Table 1 below.

Table1. Incumbent and replacement DO probe identification

	Product Number	Description
Current DO Probe accessory	817-00145	Probe, DO, VisiFerm 225 (ECS Mode), Hamilton
New DO Probe accessory	29749610	Sensor, DO, HAM VisiFerm RS-485 ECS, Optical, VP8

Change description

The DO probe accessory will be replaced due to end-of-life (EOL) by the supplier. The new DO sensor (VisiFerm RS485-ECS) is the supplier's replacement product and is equivalent or better in comparison to the current DO sensor (VisiFerm DO ECS). The new DO probe is backwards compatible with H0/H2 caps, providing equivalent process wetted components.

Impact of change

There is no impact to the fit of the new probe as it is backward compatible to the with the H0/H2 caps. The new probes also provide equivalent process wetted components, so there is no impact to regulatory claims including animal origin.

There is no change of supplier for the new probe. The new probe family directly replaces the incumbent probe. The wetted parts in the replacement DO sensor fulfil the current material specifications and requirements.

Qualification plan

Supplier qualifications

Electrical and functional verification testing of the replacement DO sensor have been performed with passed results showing equal functionality.

Cytiva qualification

Cytiva internal testing of the new probe consisted of tests to confirm wiring communication, accuracy and repeatability when integrated in the application assembly.

Once the system setup was completed with critical alarms on the interface, the DO probe was connected to the test bag and calibrated. Gases for testing were introduced into the bag and appropriate stabilization time was observed. Upon stabilization, the DO values were recorded. Testing was repeated multiple times for both primary and secondary cables. Passing results indicated that the measured DO value was within the acceptance criteria.

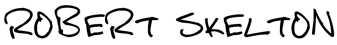
Qualification results

All samples passed qualification testing. Cytiva has reviewed the results of both supplier and internal qualification testing and has determined that the new 29749610 *Sensor, DO, HAM VisiFerm RS-485 ECS, Optical, VP8* is acceptable and suitable for use as a replacement for the 817-00145, *Probe, DO, VisiFerm 225 (ECS Mode), Hamilton* accessory probe.

Implementation of change

The discontinuation of the current (817-00145) and availability of the replacement DO sensor (29749610) is to be implemented and available as a new accessory immediately.

Sincerely,

DocuSigned by:

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Robert Skelton
Sr. Regulatory Support Manager

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